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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/589,862

04/30/2007

Suresh Pareek

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EXAMINER

TRAN, SUSAN T

ART UNIT

PAPER NUMBER

1615

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/589,862	PAREEK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	SUSAN TRAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 October 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/08/10 has been entered.

### ***Claim Rejections - 35 USC § 103***

*Claims 1-8, 11-15 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. US 2004/0028737, in view of Mehra et al. US 5,733,575.*

Deshpande teaches an enteric coating composition comprising methacrylate copolymer type C, polyethylene glycol 600, titanium dioxide, and talc (examples 1-4 and 8). The amounts of the above components disclosed in the examples fall within the claimed ranges, e.g., about 60% methacrylate copolymer type C, about 6% plasticizer, about 7% opacifier, and about 24% detackifier.

Deshpande does not expressly teach that the coating composition is in powder form.

Mehra teaches a powder coating composition that is non-toxic and edible. The powder coating composition comprising enteric film forming polymer (abstract; and columns 3-4). Thus, it would have been obvious to one of ordinary skill in the art to

Art Unit: 1615

prepare a coating composition in powder form in view of the teachings of Mehra to obtain the claimed invention. This is because Mehra teaches a dry powder coating that can overcome the disadvantages of the known aqueous coating compositions (column 1), because Mehra teaches a dry powder coating composition that is non-toxic and edible, because Mehra teaches that a dry powder coating composition provides an enteric coating that is less tacky and does not have the odor of ammonium hydroxide, and because Mehra teaches that a dry powder coating composition is known in the art.

*Claims 9, 10, 16 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Deshpande et al. US 2004/0028737, in view of Mehra et al. and Kokubo et al. US 4,948,622.*

Deshpande is relied upon for the reason stated above. Deshpande does not expressly teach the use of pigment in the coating composition.

Kokubo teaches a coating composition comprising edible dyes, and edible lake pigments (column 3, lines 45-50). Thus, it would have been obvious to one of ordinary skill in the art to modify the coating composition of Deshpande to include the use of edible pigments in view of the teachings of Kokubo to obtain the claimed invention. This is because Kokubo teaches that the present of pigment in a coating composition is well known in the art.

***Response to Arguments***

Applicant's arguments filed 09/08/10 have been fully considered but they are not persuasive.

Applicant argues that Deshpande discloses the use of 2M ammonia solution to adjust pH to neutrality 7-7.5 when methacrylate copolymer of Type C is included (see abstract and examples 1-4 in paras. [0045] and [0049] on page 3 and [0053] and [0057] on page 4), and the reference fails to disclose that the enteric coating composition does not include an alkalinizing agent when the methacrylate copolymer of Type C is included in an amount of about 20-90 wt% in the enteric coating dry powder composition as claim 1 recites (see *id.*). The alkalinizing agent is explained in the specification by referring to Lehmann et al. (U.S. Patent No. 4,520,172) and Chittamuru et al. (U.S. Patent No. 6,420,473), both of which are incorporated by reference into the specification (see page 2, lines 7-15 of the specification). Lehmann discloses ammonia as a particularly effective alkali and further discloses that an ammonia solution is added to emulsion polymer of methacrylic acid and ethyl acrylate (see coin. 4, lines 52-65 and example 3 in colns. 6-7). Chittamuru lists ammonium compounds such as ammonium carbonate and ammonium bicarbonate, which provides an ammonium ion when dissolved in an aqueous solution, as an alkalinizing agent of a carboxylic acid group in an acrylic resin (see abstract and coln. 4, lines 6-34). Thus, the specification of the present application clearly indicates the ammonia solution as the alkalinizing agent. The alkalinizing agent stabilizes the coating resin by neutralizing free carboxylic acid groups, which destabilize the coating resin (see page 2, lines 26-31 of the specification).

Art Unit: 1615

Generally, when the free carboxylic acid groups are not neutralized, the composition is not stable, and the coating would not be resistant to stomach environment (see page 3, lines 1-9 of the specification). In contrast, without using the alkalinizing solution, the dry powder composition of claim 1 can be stable and stored for long time, have no caking or no agglomeration, and provide the coating with good tensile strength without tack (see page 2, line 18 - page 3, line 9). Also, without using the alkalinizing agent, i.e., without neutralizing the composition, the enteric coating provided with the dry composition of claim 1 would not include a salt formed from the ammonium agent and free acid(s) (see *id.*). Moreover, because the neutralizing step with the alkalinizing agent is not necessary, concentrations of the components in the dry powder composition of claim 1 do not vary by adding the alkalinizing agent, which may vary or might be added in an excess amount and exist in the coating suspension as a free alkali. By eliminating the alkalinizing agent from the composition, the enteric coating using the composition of claim 1 would not only reduce the handling time during coating the substrates, particularly in industrial scale manufacturing, but also ensure the uniform quality of the coating suspension such as uniform concentrations of the components in the coating composition, no salt formed with the alkalinizing agent, and no free alkali in the suspension as discussed above. The reference, which uses the alkalinizing agent, cannot enjoy these advantages. Accordingly, claim 1 is distinguished from Deshpande.

In response to Applicant's arguments, however, Applicant's attention is called to Examples 5-7, where Deshpande teaches the use of methacrylate copolymer Type C

Art Unit: 1615

without the use of 2M ammonia solution. Hence, the rejection over Deshpande is maintained.

Applicant argues that Mehra discloses inclusion of an alkalizing agent in an enteric film coating dry powder composition, does not remedy the deficiencies of Deshpande.

However, in response to applicant's arguments, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Mehra is cited solely for the teaching of coating composition in powder form is known in the art.

### ***Correspondence***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to S. Tran whose telephone number is (571) 272-0606.

The examiner can normally be reached on M-F 8:30 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert A. Wax can be reached on (571) 272-0623. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. Tran/  
Primary Examiner, Art Unit 1615